PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	The At Home/Chez Soi trial protocol: A pragmatic, multi-site, randomized controlled trial of a Housing First intervention for homeless individuals with mental illness in five Canadian cities
AUTHORS	Paula N. Goering, David L. Streiner, Carol Adair, Tim Aubry, Jayne Barker, Jino Distasio, Stephen W. Hwang, Janina Komaroff, Eric Latimer, Julian Somers, Denise M. Zabkiewicz

VERSION 1 - REVIEW

REVIEWER	Robert Rosenheck MD, Seniuor Investigator VA New England Mental Illness Research and Education Center Professor of Psychiatry Yale Medical School USA
REVIEW RETURNED	25/08/2011

THE STUDY	None
RESULTS & CONCLUSIONS	None
REPORTING & ETHICS	None
GENERAL COMMENTS	This is a complex and very ambitious study. It represents a major investment of public funds in an effort to evaluate the cost-effectiveness of multiple strategies to help homeless people with mental health problems exit from homelessness and improve their health, quality of life, and community functioning. It will test a currently popular approach called Housing First which has been shown to be effective for severely mentally ill people with co-morbid addiction problems as well as a lower intensity model of intensive case management and several locally conceived approaches to assisting this highly vulnerable population. It will include large samples at each of five sites and aspires to pool data across sites if possible, and to allow each site to analyze its own data. It proposes to develop an algorithm for differentiating clients who "need" high intensity services and those whose needs are of lesser magnitude. Well informed proposals are made do address the anticipated problems of missing data and to conduct cost-effectiveness analyses. Useful measures are identified in numerous domains, balancing the desire for extensive information with the practical limits on data collection burden. The study plan thus reflects a very high level of expertise in the substantive area of helping homeless people with mental health problems and in the methodological areas of program evaluation and cost-effectiveness analysis. This brief protocol summarizing a very large initiative is thus a tour de force of expertise in multiple areas and readers can learn a good deal from it. The major issue it raises concerns whether such an ambitious study can fulfill its potential. Will local sites have the capacity and incentive to fully analyze their data? Have resources been

	provided for the primary investigators to spend the many years it will take to reap the harvest of knowledge that this study promises to yield. Is it better to answer one question well in a large study, or to try to address many smaller questions, as is the case here? All too often major studies are adequately funded to collect their proposed data but once the study is completed the investigators have to move on to the next grant to fund themselves. Some would say the yield would be greater from multiple smaller studies but that question cannot be answered in advance. A large exceptionally expensive study of this kind typically has a complex political context that does not appear in the scientific plan. There is, no doubt, a back story that shaped its objectives and designs. The fundamental question a study like this raises is the cost-effectiveness of large scale research. There have a been only a few studies on this scale in the mental health field. The Robert Wood Johnson Program on Chronic Mental Illness, Fort-Bragg Demonstration on integrated care in child psychiatry, the ACCESS program on community-level systems integration of homeless services, and perhaps the CATIE trial of atypical antipsychotics in Schizophrenia and Alzheimer's disease may be useful reference points for thinking about this kind of research. At a more "micro" level, in spite of this very high quality of the proposal, issues that could be better developed are the stratification of subjects into high and low levels of need, the measures of model fidelity, and even the main outcome measure of "housing stability." The housing first model as conceptualized is very complex, but there is no evidence thus far as to whether the intensive case management and the even vaguer notions of recovery culture and choice models add anything to the basic provision of housing subsidies. There is a conflict between claiming to let the clients make all choices and forcing them to hand over their money for rent and have a weekly home visit. Most studies have failed to find benefit from intensive case management over less intensive care and suggest that the housing subsidy is the active ingredient. This study is not designed to shed further light on this important issue. In the end, the authors are to be congratulated on an outstanding scientific design and on what must have been a complex, largely political (in a good sense), effort to obtain support for a colossal endeavor. Good luck and bon chance! Robert Rosenheck MD VA New England Mental Illness Research and Education Center Yale Medical School

VERSION 1 – AUTHOR RESPONSE

Response to Reviewer's comments

We are grateful for the helpful advice from the managing editor about how to improve the reporting of the study and for the positive and thought-provoking responses of a distinguished expert in the field of mental health services research.

For more complete reporting we have modified the title of the study (p.1) and specified its dates (p5). Strategies for ensuring engagement (p.6) and promoting continued participation (p.8,9) are now described. More detail has been provided about gaining consent (p.10), randomization mechanisms (p.10) and we have made clear that it is an unblinded study (p.7). We modified the headings and description of Table 1 (p.7) to communicate more clearly our plans for data collection and have added an appendix C (p.7) that describes the study instruments in more detail. Criteria for discontinuing allocated intervention are given (p.11). Plans for data entry, quality

control (p.8), and interim analyses (p.14) are described. We have added information about data storage, maintenance and access (p.14, 15). The funding statement contains a fuller description of the roles of study sponsors. (p.15) In response to the second reviewer's "micro" level feedback, we have expanded our description of the fidelity scale(p.12), and our housing stability definition (p.13), as well as adding an appendix D (p.10). that gives more detail about the stratification into high and low need.

At the more "macro" level, it is good to have the ambitious scope of the project and the extensive expertise that went into its design recognized by Dr. Rosenheck, who has carried out many large, well known multi-site studies in this area.

We are heedful of his concern that the pay off for such a large research investment may not be realized due to insufficient time and resources to analyze and write up the massive data. We have a large group of ambitious, experienced investigators across the country committed to publishing the core findings. They bring with them students and trainees who will assist us to reach our goals by conducting supplementary studies. The data that we are gathering will be available after the study ends and some co-investigators are now writing grant applications to ensure that there are resources to support post-study activity. Our publications policy and procedures are set up to encourage high quality, timely submissions to interdisciplinary journals. Time will tell whether these strategies are successful.

As Dr Rosenheck points out, studies of this magnitude are not just scientific enterprises.
We are documenting with qualitative methods the "back story" of the conception and implementation of the project so that others can learn about the social and political aspects of these processes. Evaluation of the impact and cost effectiveness of large scale research projects such as this one is an important issue that can only be answered by a longer term, multi-faceted meta-evaluation. We are comforted by knowing that the project will offer opportunities that would not otherwise be there for hundreds of participants to be housed and have the supports that may assist them to change cycles of homelessness and poor health.

The question he raises of what is added to the basic provision of housing by the Housing First program model is challenging. We are interested in the critical ingredients of Housing First and will use a mixed methods approach to understanding them better. Interviews with participants will also ask about their experiences related to choice and will shed light on their reactions to the minimal requirements of the intervention.
The question of whether housing subsidies alone, or with less intensive supports, might be effective is not one that this study can answer. We considered it as an option and felt that landlords, participants and their neighbors would not be well served without the offer of a compassionate relationship and access to comprehensive services to those who struggle to overcome chronic homelessness and severe mental illness. The extent to which participants accept this offer will provide some test of whether this assumption is correct